H. R. 698

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of certain prescription drugs by pharmacists and wholesalers.

IN THE HOUSE OF REPRESENTATIVES

February 14, 2001

Mr. Sanders (for himself, Mr. Deutsch, Mr. Shows, Mr. Brown of Ohio, Mr. Bonior, Ms. Kaptur, Ms. DeLauro, Mr. Conyers, Mr. Nadler, Mrs. Mink of Hawaii, Mr. Oberstar, Mr. Crowley, Mr. Abercrombie, Mr. DeFazio, Mr. Hilliard, Mr. Filner, Mr. Olver, Mr. Lafalce, and Mr. Hinchey) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of certain prescription drugs by pharmacists and wholesalers.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Prescription Re-
- 5 importation, Improvement, Correction, and Enhancement
- 6 Act".

1	SEC. 2. AMENDMENTS TO PROGRAM FOR IMPORTATION OF
2	CERTAIN PRESCRIPTION DRUGS BY PHAR-
3	MACISTS AND WHOLESALERS.
4	Section 804 of the Federal Food, Drug, and Cosmetic
5	Act (as added by section $745(e)(2)$ of Public Law 106 –
6	387) is amended—
7	(1) by striking subsections (e) and (f) and in-
8	serting the following subsections:
9	"(e) Testing; Approved Labeling.—
10	"(1) Testing.—Regulations under subsection
11	(a)—
12	"(A) shall require that testing referred to
13	in paragraphs (6) through (8) of subsection (d)
14	be conducted by the importer of the covered
15	product pursuant to subsection (a), or the man-
16	ufacturer of the product;
17	"(B) shall require that, if such tests are
18	conducted by the importer, information needed
19	to authenticate the product being tested be sup-
20	plied by the manufacturer of such product to
21	the importer; and
22	"(C) shall provide for the protection of any
23	information supplied by the manufacturer
24	under subparagraph (B) that is a trade secret
25	or commercial or financial information that is
26	privileged or confidential.

1	"(2) Approved labeling.—For purposes of
2	importing a covered product pursuant to subsection
3	(a), the importer involved may use the labeling ap-
4	proved for the product under section 505, notwith-
5	standing any other provision of law.
6	"(f) Discretion of Secretary Regarding Test-
7	ING.—The Secretary may waive or modify testing require-
8	ments described in subsection (d) if, with respect to spe-
9	cific countries or specific distribution chains, the Secretary
10	has entered into agreements or otherwise approved ar-
11	rangements that the Secretary determines ensure that the
12	covered products involved are not adulterated or in viola-
13	tion of section 505.";
14	(2) by striking subsections (h) and (i) and in-
15	serting the following subsections:
16	"(h) Prohibited Agreements; Nondiscrimina-
17	TION.—
18	"(1) Prohibited agreements.—No manufac-
19	turer of a covered product may enter into a contract
20	or agreement that includes a provision to prevent
21	the sale or distribution of covered products imported
22	pursuant to subsection (a).
23	"(2) Nondiscrimination.—No manufacturer
24	of a covered product may take actions that discrimi-
25	nate against, or cause other persons to discriminate

1 against, United States pharmacists, wholesalers, or 2 consumers regarding the sale or distribution of cov-3 ered products. "(i) STUDY AND REPORT.— "(1) STUDY.—The Comptroller General of the 6 United States shall conduct a study on the imports 7 permitted under this section, taking into consider-8 ation the information received under subsection (a). 9 In conducting such study, the Comptroller General shall— 10 "(A) evaluate importers' compliance with 11 12 regulations, determine the number of ship-13 ments, if any, permitted under this section that 14 have been determined to be counterfeit, mis-15 branded, or adulterated; and "(B) consult with the United States Trade 16 17 Representative and United States Patent and 18 Trademark Office to evaluate the effect of im-19 portations permitted under this section on trade 20 and patent rights under Federal law. 21 "(2) Report.—Not later than 5 years after the 22 effective date of final regulations issued pursuant to 23 this section, the Comptroller General of the United

States shall prepare and submit to Congress a re-

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1	port containing the study described in paragraph
2	(1).";
3	(3) in subsection $(k)(2)$ —
4	(A) by redesignating subparagraphs (A)
5	through (E) as subparagraphs (B) through (F),
6	respectively; and
7	(B) by inserting before subparagraph (B)
8	(as so redesignated) the following subpara-
9	graph:
10	"(A) The term 'discrimination' includes a
11	contract provision, a limitation on supply, or
12	other measure which has the effect of providing
13	United States pharmacists, wholesalers, or con-
14	sumers access to covered products on terms or
15	conditions that are less favorable than the
16	terms or conditions provided to any foreign pur-
17	chaser of such products.";
18	(4) by striking subsection (m); and
19	(5) by inserting after subsection (l) the fol-
20	lowing subsection:
21	"(m) Funding.—For the purpose of carrying out
22	this section, there are authorized to be appropriated such
23	sums as may be necessary for fiscal year 2002 and each
24	subsequent fiscal year.".